

## REMARKS

With entry of the amendment, claims 1-9 are pending in the application. In the March 15, 2002 Office Action, claim 1 was rejected under 35 U.S.C. 101; claims 1-10 were rejected under 35 U.S.C. 112, second paragraph; ; claims 1-10 were rejected under 35 U.S.C. 112, first paragraph; claims 1-4 and 10 were rejected under 35 U.S.C. 102(b); and claims 5-10 were rejected under 35 U.S.C. 103(a). In view of the amendments above and arguments below, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

A telephonic interview, which included Examiner Moonan, inventors Michael Velde and Paul Sun, and the undersigned, was held on July 8, 2002. Applicants thank Examiner Moonan for the courtesy of his time. The interview focused primarily on the rejection of claims under 35 U.S.C. 112, first paragraph and is summarized below under the corresponding heading.

### Rejection under 35 U.S.C. 101

Claim 10 was rejected as being drawn to nonstatutory subject matter. The Examiner asserted that the seed of claim 10 is broadly drawn to any alfalfa plant population, and that the plant population as claimed would have the same characteristics as those found in nature, and therefore, does not constitute patentable subject matter. Claim 10 is drawn to seed produced according to the method of claim 5. Applicants respectfully submit that the seed of claim 10, harvested from plants grown from males sterile and male fertile alfalfa plants planted in a ratio of about 4:1, would not have the same characteristics as those found in nature. The genetic composition of the seeds would be different than that of seed found in nature, in that a much higher percentage of the seed would come from a parent that is a cytoplasmic male sterile alfalfa plant than would be found in nature. However, in the interest of advancing prosecution, Applicants have cancelled claim 10 without prejudice to filing a continuation thereon.

### Rejections under 35 U.S.C. 112, second paragraph

Claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph for the recitation of "ATCC Accession Number XXXXX". Claim 1 and claim 2, from which claims 3 and 4 depend, have been amended to include ATCC Accession Number PTA-2759.

Claim 2 stands rejected under 35 U.S.C. 112, second paragraph for the recitation of “derived” in view of the definition of “hybrid” as defined in the specification at page 6, lines 6-8. The term “derived” is defined in the specification at page 3, line 29-page 4, line 2 as a plant grown directly from seed deposited ATCC Accession Number PTA-2759, or obtained from a vegetative cutting, seed, callus, or tissue culture obtained from a plant or plant part grown from the seed deposited as Accession Number PTA-2759.

Claim 5, and claims 6-10, which depend from claim 5, are rejected under 35 U.S.C. 112, second paragraph for the recitation of “controlled pollination” because the Examiner stated that the pollination does not appear to be controlled by any operative. Applicants respectfully submit that the term “controlled pollination” is well understood by one skilled in the art and request withdrawal of the rejection.

Claims 5, and claims 6-10, which depend from claim 5, are rejected under 35 U.S.C. 112, second paragraph for the recitation of “selectively harvesting seed from the cytoplasmic male sterile hybrid plants of step (a)” because it is unclear to the Examiner what is meant by “selectively harvesting”. Applicants submit that it is clear from the language of the claim and from the specification (e.g., see page 5, lines 25-27) that Applicants intended to convey seeds selectively harvested from male sterile plants are harvested from male sterile plants, as opposed to male fertile plants.

Claims 5, and claims 6-10, which depend from claim 5, are rejected under 35 U.S.C. 112, second paragraph for the recitation of “allowing pollination”. Applicants have amended claim 5 for reasons unrelated to patentability to clarify that pollination occurs by allowing “open” pollination.

Claim 7 was rejected under 35 U.S.C. 112, second paragraph for the recitation of the phrase “is accomplished employs”. In the interest of advancing prosecution on the merits, and for reasons unrelated to patentability, Applicants have amended claim 7 to include the Examiner’s suggested language, i.e., that the step of determining “the hybridity of the progeny of the crossing is with” a genetic or morphological marker.

Claim 8 was rejected under 35 U.S.C. 112, second paragraph for the recitation of the phrase “determining the hybridity is accomplished by amplified fragment length polymorphism analysis.” The Examiner stated that “Amplified fragment length polymorphism analysis has no ‘determining’ capability of its own” and stated that substituting “with” for “by” would overcome this rejection. Applicants submit that one of skill in the art would understand what is meant by the claim language. However, in the interest of advancing prosecution on the merits, and for reasons unrelated to patentability,

Applicants have amended claim 8 to replace “by” with “with” according to the Examiner’s suggestion.

Claim 9 was rejected under 35 U.S.C. 112, second paragraph for the recitation of the phrase ‘wherein the average seed yield of step (d) is at least 80% of the average seed yield obtainable by crossing the male fertile plant of step (c).’ The Examiner asserted that the claim is confusing because the seed yield of step (d) includes exactly the seed yield produced by crossing by open pollination with the fertile plant of step (c) to the second generation male sterile plants recited in step (c). Applicants respectfully submit that it would be clear to one skilled in the art that claim 9 requires that the average seed yield of step (d) be at least 80% of the average seed yield of obtainable by crossing only the male fertile plant of step (c).

#### Rejections under 35 U.S.C. 112, first paragraph

Claim 1-10 stand rejected under 35 U.S.C. 112, first paragraph as not being described in the specification in such a way as to enable one skilled in the art to make or use the invention. The Examiner asserts that claim 1 is drawn to any *Medicago sativa* or cultivated alfalfa seed derived with the synthetic variety Thor. The Examiner stated that interpretation of the ATCC Accession Number under which the hybrid seed was deposited was made in light of the disclosure, and cited specifically page 2, lines 6-10, which the Examiner characterized as describing to one of skill in the art a plant made with a series of alfalfa plants with arbitrary names and a population of genetically segregating alfalfa plants comprising the synthetic variety Thor. The Examiner broadly interpreted the names DS9705Hyb, A833, B209, DS9761, and C580 as “synthetic varieties”.

Based on the Examiner’s interpretation of the components as being synthetic varieties, the Examiner has rejected claims 1-4 as not being enabled, even though the Applicants have deposited seed with the ATCC, because the Examiner asserted that the seed deposit would be inadequate to contain a representative number of the greater than 1 billion plants that the opined would be represented by the crossing.

During the July 8, 2002 telephonic interview, the Applicants explained that, as disclosed in the specification, the hybrid components of the claimed invention are not synthetic varieties, but rather, selected clones of alfalfa. The Examiner asserted that the specification does not support that interpretation.

Applicants respectfully disagree with the Examiner’s interpretation. Based on the specification, one skilled in the art would appreciate that the claimed invention was made using selected parental components, as opposed to a commercial variety. For example, the

description of the method of the invention at page 4, line 29-page 5, line 12 (reproduced below), clearly indicates that the method employs selected lines or clones of alfalfa:

Briefly, the method of the invention is performed as follows:

1. **Alfalfa plants with desirable agronomic traits are selected.** Male sterile A line plants are selected from male sterile ("female") populations, maintainer B line plants are selected from maintainer populations, and **pollenizer C line plants are selected from restorer populations, or from clonal or synthetic populations.**
2. The selected A and B lines are grown from cuttings or seed and cross pollinated using bees to produce hybrid male sterile breeder and foundation seeds. Seeds are harvested from cytoplasmic male sterile plants only.
3. **Selected pollenizer plants are selfed or interpollinated by bees to produce breeder and foundation pollenizer seeds and the seed is harvested in bulk.**
4. For large scale commercial production of hybrids, male sterile seeds and pollenizer seeds are planted at a ratio of male sterile seeds and male fertile (pollenizer) seeds of about 4:1, and the plants grown therefrom are pollinated.
5. Seeds are harvested in bulk from the plants grown from the seed of step 4, above.
6. Optionally, the percentage hybridity can be determined using either genetic or morphological markers.

Applicants describe the alfalfa plants used to develop the seed and method of the invention as alfalfa lines at page 6, lines 1-4 (reproduced herein below).

In the examples below, male sterile line A833, maintainer line B209, and pollenizer lines Thor, DS9671, and C580 were used. One of ordinary skill in the art will appreciate that any suitable male sterile line, maintainer line, and pollenizer line could be successfully employed in the practice of the method of the invention.

Contrary to the Examiner's interpretation of parental components A833, B209, Thor, DS9671, and C580 as being synthetic varieties, Applicants described the plants identified by these terms as being alfalfa plant lines.

Further, throughout the specification, the Applicants made clear that the terms Thor, DS9671, C580, and B209 were intended to refer to using selected clones, or the S1 progeny of selected clones, rather than commercial varieties (e.g., please see page 7, lines 10-12). As Dr. Sun explains in his declaration at page 2, paragraph 7 a pollenizer line is understood by one of skill in the art to mean "a group of individuals from a common ancestry, which is narrower than a strain or variety". One of ordinary skill in the art would understand that a

plant clone is a plant or group of plants originated by vegetative propagation from a single plant.

Throughout the specification, Applicants clearly distinguished between synthetic varieties (Vernal and Saranac) and selected clones (Thor, DS9761, and C580). For example, beginning on page 7, the Examples detail studies in which characteristics of synthetic varieties (Vernal and Saranac) were compared with those of the (S1) progeny of selected clones (Thor, DS9761, and C580). Characteristics of hybrids of crosses between a male sterile line (A833) and a maintainer line (B209), and hybrid DS9705Hyb, the components of which include a cytoplasmic male sterile hybrid plant (A833xB209), and selected pollenizer lines of were also compared. Tables 1-23 compare various traits of synthetic varieties Saranac and Vernal with those of hybrid (A833xB209), hybrid DS9705Hyb, and with those of the S1 progeny of selected clones of B209, A833xB209, Thor, DS9671, and C580 (the hybrid components of DS9705Hyb).

One of skill in the art appreciates that in order to evaluate hybridity, one compares the characteristics of plants grown from a crossing with those of the parental components. At page 10 of the specification, Applicants describe assessing the hybridity of the hybrid DS9705Hyb by selfing plants of the parental lines B209, DS9671, C580, and Thor to generate pure S1 seed, and isolating DNA from plants grown from the S1 seed for subsequent analysis. One skilled in the art would appreciate that the parental components of the hybrid DS9705Hyb were S1 progeny of selected clones of B209, A833xB209, Thor, DS9671, and C580, not synthetic varieties.

The Examiner asserted that claim 5, and claims 6-10, which depend from claim 5, are not enabled because the making of cytoplasmic male sterile alfalfa plants is unpredictable and genotype specific, and would therefore require undue experimentation. Applicants respectfully disagree with the Examiner's position.

Factors to be considered in determining what constitutes "undue experimentation" were set forth in *In re Wands*, 858 F.2d 731, 737; 8 USPQ 2d 1400 at 1404 (Fed. Cir. 1988) are: (1) the breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability; (6) amount of direction or guidance provided; (6) existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants submit that the claims are not unduly broad relative to the disclosure. Applicants have described at page 4, lines 3-27 of the instant application how to identify cytoplasmic male sterile plants and have provided working examples. The level of one of

ordinary skill in the art of alfalfa plant breeding is high, and based on the direction and guidance provided, it would be well within the ability on one skilled in the art to identify a cytoplasmic male sterile alfalfa plant for use according to the claimed method.

The Examiner asserted that Applicants have failed to provide sufficient guidance as to how one would go about assessing the percent hybridity. Applicants provided an example of one method by how one would go about determining the percent hybridity using molecular markers. Determining the percent hybridity is routinely used in plant breeding and is well within the ability of one of ordinary skill in the art. Applicants note the Examiner's characterization of Sun et al. (U.S. Patent No. 4,045,912, which is incorporated by reference in the instant application) in the Office Action (page 15, third paragraph) "Sun et al. teach in Table II the determination of the hybridity of the open pollination step." Applicants submit that the claims are fully enabled by the disclosure.

Rejections under 35 U.S.C. 102(b)

The Examiner has rejected claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Northrup et al. (Seed Scoop 19:4-6, 1972). This rejection is based on the Examiner's interpretation of A833, B209, DS9761, and Thor as being designations for synthetic populations or varieties, and on the Examiner's interpretation of "derived from" as including an unexemplified number of plant crosses or plant generations. The Examiner also interpreted DS9671, C580, and B209 to include Thor. As Applicants described in the specification and explained above, the pollinizer plants used as parental components to produce the seed of claim 1 were selected on the basis of desirable agronomic characteristics and selfed or interpollinated to obtain breeder and foundation seed. These select clones are distinct from grown from synthetic varietal seed. A833 is a cytoplasmic male sterile line and B209 is a maintainer line, each of which was selected as described in the specification. Applicants respectfully submit that none of the plants obtainable by growing the seed of claim 1 is identical to plants grown from synthetic seed.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (US Patent No. 4,045,912), and under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Viands et al. in light of Pedersen et al. Applicants have cancelled claim 10 without prejudice, rendering moot this rejection.

Rejections under 35 U.S.C. 103(a)

Claims 5, 6, 9, and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. The Examiner asserts that Sun et al. (US Patent No. 4, 045,912) teaches a method of making alfalfa seed with 76.3 or 85% hybridity using a ratio of 3:1 male sterile to male fertile seed. The Examiner also asserts that Sun et al. teach increases in the percent hybridity obtained with increasing ratios of male sterile to male fertile alfalfa plants. The Examiner concluded that it would have been "an obvious design choice by one of ordinary skill in the art to utilize the method for producing a synthetic variety taught by Sun et al. and modify the ratio of pollenizers from the 3:1 ratio taught by Sun et al., ... to design a method with a 4:1 ratio which could make alfalfa plant with at least an 85% increase in seed yield as broadly claimed."

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness, which requires: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) the art reference or combination of references must teach all of the claimed limitations (MPEP 2142). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143).

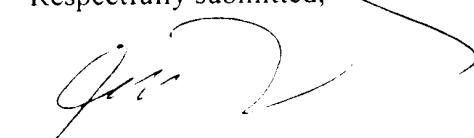
As the Examiner acknowledged, Sun et al. does not teach or suggest practicing a method of producing alfalfa seed having at least 75% hybridity comprising crossing male sterile hybrid alfalfa by male fertile alfalfa plants planted in a ratio of about 4:1, as required by independent claim 5 and its dependent claims 6-9. In fact, Sun et al. teaches away from increasing the ratio of male sterile to male fertile plants to greater than about 3:1. Sun et al. teaches that male sterile alfalfa have reduced seed yield relative to male fertile alfalfa (column 1, lines 34-37), and that in order to obtain maximum seed production, "the ratio of male sterile to male fertile alfalfa plants must be in the range of 1:1 to 3:1" (column 3, lines 13-17). Because alfalfa breeders are generally concerned with optimizing seed yield, one of ordinary skill in the art would not be motivated to modify the disclosure of Sun et al. to make the claimed invention, and in fact, would be discouraged from making the claimed invention. Therefore, claim 5 is not obvious over Sun et al. Similarly, claims 6-9, which depend from and further limit claim 5, are not obvious over Sun et al. Applicants have cancelled claim 10, rendering moot its rejection under 35 U.S.C. 103(a).

Claims 5-7 stand rejected under 35 U.S.C. 103(a) as being obvious over Sun et al. in view of Viands, and claims 5 and 8 stand rejected as being obvious over Sun et al. in view of Rotili, further in view of Vos. None of Viands, Rotili, or Vos cures the deficiency of the primary reference.

As the claims are now in condition for allowance, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

This response, which is being filed within three months of the expiration of the shortened statutory period for reply, is accompanied by a petition for a three-month extension of time and by check number 45254 in the amount of \$460 to cover the fee required under 37 C.F.R. 1.17(a)(3). No other fee is believed due in connection with this submission.

Respectfully submitted,



Jill A. Fahrlander  
Reg. No. 42,518

Docket No.: 87165-9051  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue  
Milwaukee, Wisconsin 53202-4108

(608) 283-0124

## MARKED-UP VERSION OF THE CLAIMS

1. A *Medicago sativa* or cultivated alfalfa seed deposited as ATCC Accession Number [XXXXX] PTA-2759.
2. A *Medicago sativa* hybrid or cultivated alfalfa plant derived from seed deposited [deposited] as ATCC Accession Number [XXXXX] PTA-2759.
5. A method of producing alfalfa seeds having at least 75% hybridity comprising the steps of :
  - (a) crossing by controlled pollination cytoplasmic male sterile alfalfa plants with maintainer line alfalfa plants to produce cytoplasmic male sterile hybrid plants;
  - (b) selectively harvesting seed from the cytoplasmic male sterile hybrid plants of step (a);
  - (c) crossing male sterile hybrid alfalfa plants by male fertile alfalfa plants by allowing open pollination of plants grown from the seed of step (b) and seed from at least one [variety] line of male fertile alfalfa plants, the male sterile seed and male fertile seed planted at a ratio of about 4:1; and
  - (d) non-selectively recovering the seeds from the pollinated alfalfa plants of step (c).
7. The method of claim 6, wherein the step of determining the hybridity [is accomplished employs] of the progeny of the crossing is with a genetic or morphological marker.
8. The method of claim 6, wherein the step of determining the hybridity is accomplished [by] with amplified fragment length polymorphism analysis.
9. The method of claim 5, wherein the average seed yield of step (d) is at least 80% of the average seed yield obtainable by crossing only the male fertile [plant] plants of step (c).